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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,299	12/28/2000	Mark Madden	DIVER1440-2	8629

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/05/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,299

Applicant(s)

MADDEN ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. The sequence listing, filed on May 11, 2002, and the information disclosure statement, filed on September 10, 2001, have been entered. Claims 1-30 are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
- I. Claims 1-17 and 22-24, drawn to methods of making α -substituted carboxylic acids using nitrilases, classified in class 435, subclass 136.
 - II. Claims 18-21, drawn to α -substituted carboxylic acids, classified in class 562, subclass 557.
 - III. Claims 25 and 29, drawn to nitrilase polypeptides related to SEQ ID NO:2, classified in class 435, subclass 227.
 - IV. Claims 25 and 30, drawn to nitrilase polypeptides related to SEQ ID NO:4, classified in class 435, subclass 227.
 - V. Claims 26 and 27, drawn to nucleic acid sequences encoding nitrilase polypeptides related to SEQ ID NOs: 1 and 2, classified in class 536, subclass 23.2.
 - VI. Claims 26 and 28, drawn to nucleic acid sequences encoding nitrilase polypeptides related to SEQ ID NOs : 3 and 4, classified in class 536, subclass 23.2.

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3. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the carboxylic acids can be made by a materially different process of making the claimed product, such as organic synthetic methods with extensive purification to produce the enantiomerically pure claimed acid. Thus, Groups I and II are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group I is related to Groups III and IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nitrilases can be used for a materially different process of using that product, such as in the production of antibodies. Thus, Group I is patentably distinct from Groups III and IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Group I is related to Groups V and VI because the nitrilase used in the methods of Group I can be recombinantly produced using the nucleic acids of Groups V and/or VI. However, the methods of Group I do not use the nucleic acids. Moreover, the nucleic acids are wholly

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different products from the nitrilases used in the methods and from the α -carboxylic acids produced in the methods. Thus, Group I is patentably distinct from Groups V and VI. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The α -carboxylic acids of Group II are related to the nitrilase polypeptides and encoding nucleic acids of Groups III-VI because the nitrilase can be used to produce the α -carboxylic acids. However, both the nucleic acids and the polypeptides have other uses and are wholly different compounds, both structurally and functionally, than the α -carboxylic acids. Thus, Group II is patentably distinct from Groups III-VI. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The nitrilases of Groups III and IV are related as functionally similar enzymes as disclosed in the specification. However, these Groups are distinct, each from the other, by virtue of their distinct structures. Each SEQ ID NO has a different structure that is unrelated, except via the function of the enzyme, to the others. No consensus sequence describing the nitrilases is disclosed or claimed. Moreover, these enzymes are from undisclosed source(s) listed in the sequence listing as "unknown organism from environmental samples" described only using their structures; in other words, there is no description of these nitrilases having particular characteristics in common, such as pI, catalytic activity values, etc. Thus, each of these enzymes, as defined by their structures, is patentably distinct from the others. Moreover, a search of the two Groups together would be burdensome considering the entirely distinct

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structure search that would not overlap whatsoever. Thus, Groups III and IV are patentably distinct, each from the other.

For Groups V and VI, drawn to the nucleic acids encoding the nitrilases of Groups III and IV, the argument for their distinctness is analogous to that for the proteins as described above.

The DNA of Groups V and VI are related, respectively, to the enzymes of Group III and IV by virtue of the fact that the DNA encodes the enzymes. The DNA molecule has utility for the recombinant production of the enzyme in a host cell. Although the DNA and the enzyme are related, they are distinct inventions because the enzyme product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, DNA can be used for processes other than the production of enzyme, such as nucleic acid hybridization assays. Therefore, Groups III and IV are patentably distinct from Groups V and VI, respectively. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Election of Species

4. This application contains claims directed to the following patentably distinct species of the claimed inventions: **Group I**, drawn to methods of producing α -carboxylic acids, contains several species relating to the carboxylic acid produced, the cyanide used, the ammonium salt used, and the nitrilase used; and **Group II**, drawn to α -substituted carboxylic acids.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally

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held to be allowable. Currently, Group I Claims 1-4, 6, 8, 9, 14 are generic, and Group II Claims 18-21 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Election

5. A telephone call was made to George Einhorn on September 2, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Notice of Possible Rejoinder

6. The Examiner notes that if product claims in Groups II, III, and IV are found directed to an allowable product, then process claims in Group I, which are directed to processes of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Examiner's Notes

7. Claim 10 depends from itself. It would seem to appropriately depend from Claim 8 or 9; the restriction has been set forth with this in mind. Applicants are **strongly encouraged** to amend Claim 10 prior to examination for a clear Office action relating to this claim.

Conclusion

8. A complete response to the instant Office action must include an election of invention to be examined. If either Group I or Group II are elected, an election of species must also be set forth.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



KMK
September 3, 2002